

Docket No.: 18264 (64095201)

Application No.: 10/736,662

Reply to Notice of Non-Compliant Amendment mailed December 8, 2006

### **REMARKS**

In view of the foregoing amendments and following remarks, favorable reconsideration of the current office action is respectfully requested.

Claims 1, 2, 4-7 have been cancelled. Claims 3, 8-27 were previously withdrawn. New claims 28-41 have been added and are currently pending.

#### ***Election/Restrictions***

The election to prosecute Group I reflects only one aspect of the present invention, which involves using a combination of at least two testing parameters to detect premature rupture of amniotic membranes. As Applicant has explained in the Specification, these tests have not been used together as a two-part detection and validation system. Restriction of the claims to merely the use of a single species for testing is too limiting and do not appreciate the scope of the invention; hence, the new claims have been submitted to better reflect the interaction of the different element in the scope of the invention.

In view of telephonic conversation between Applicant and the Examiner on November 8<sup>th</sup>, 2006, Applicant will make a new election through filing a request for continued examination (RCE), substituting the claims as amended herein for the currently pending claims.

#### ***35 USC § 102 Rejections***

The Patent Office rejects claims 1 and 2, under 35 U.S.C. 102(e) as being anticipated by Kritzman *et al.* (U.S. Pat. No. 6,921,647). The Patent Office alleges that Kritzman *et al.* disclose a method of detecting the premature rupture of amniotic membrane involving the testing of vaginal fluid for pH and determining a result as an irreversible or stable color change (column 12, lines 23-24) in a test medium.

To be anticipatory under 35 U.S.C. § 102, a patent reference must "describe" every element recited in the claims at hand. Although the present invention involves testing a sample of vaginal secretion for its pH value using a visual indicator as an irreversible color change, the invention, as claimed, also includes a second part that detects using a visual indicator the relative level or presence in the vaginal secretion of at least one of three other species – H<sub>2</sub>O<sub>2</sub>, analytes specific to amniotic fluid, and cholesterol (or a combination of the three). The Kritzman patent does not anticipate the present invention as claimed for a combination of also testing for these other species. Hence, the rejection is overcome because the Kritzman patent does not teach or recite each limitation in Applicant's pending claims.

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### *35 USC § 103 Rejections*

The Patent Office rejects claims 1, 2 and 4-7, under 35 U.S.C. § 103(a) as being unpatentable in view of Smith *et al.* (U.S. Pat. No. 6,149,590) in combination with a paper by Cheng and Stevens, *Charge Induced Chromatic Transition of Amino Acid-Derivatized Polydiacetylene Liposomes*, *Langmuir* 1998, 14, 1974-1976 (Feb. 13, 1998). The Patent Office alleges that Smith discloses a method (abstract) of detecting the premature rupture of amniotic membrane comprising testing vaginal fluid for pH and determining a result as a color change in a test medium, and it would have been obvious to one having ordinary skill in the art at the time of invention to have used the liposomes taught by Cheng in the method of Smith because it is well-known and routine within the art to substitute known pH indicators and because Smith discloses that various pH indicators can be used.

Applicant submits that even though the presently pending claims involve testing for pH with a visual indicator, the cited references neither teach nor discuss also detecting the relative level of at least one kind of the following molecules – H<sub>2</sub>O<sub>2</sub>, amniotic analytes, and cholesterol – as a second component in a two-part validation system. The present invention, as claimed in a two-part combination using an indicator of these other species to confirm whether premature rupture of membrane has occurred or will soon occur. When a primary reference in a case of obviousness is silent about claimed elements of the present invention, and there is no motivation or teaching in the other references to include or combine the missing claimed elements, the references can not lead one of ordinary skill to derive Applicant's invention as claimed. The claimed invention is not obvious in light of the cited references. Hence, Applicant requests that this rejection be withdrawn.

### *Conclusion*

Based upon the foregoing amendments, remarks, and papers of record, Applicant believes that the pending claims 28-41, are in allowable form and patentable over the prior art of record.

Applicant believes that no extension of time is necessary to make this Response timely. Should Applicant be in error, Applicant respectfully requests that the Office grant such extension pursuant to 37 C.F.R. § 1.136(a) as necessary to make this Response timely, and hereby authorizes the Office to charge any necessary fee or surcharge with respect to said time extension to the Kimberly-Clark Worldwide, Inc. deposit account number 11-0875.

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Please direct any questions or comments to the undersigned attorney, who may be reached at: (770) 587-8606.

Respectfully submitted,

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#### CERTIFICATE OF TRANSMISSION

I, Laura L. Rubino, hereby certify that on December 22, 2006 this document is being facsimile transmitted to the United States Patent and Trademark Office, Fax No: (571) 273-8300.

By:



Laura L. Rubino